Exhibit A

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December 21, 2020

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, NJ 08101

Honorable Joel Schneider, U.S.M.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, NJ 08101

Re: IN RE: VALSARTAN, LOSARTAN, & IRBESARTAN PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Kugler and Judge Schneider:

Please accept this letter on behalf of the Plaintiffs in advance of the December 22, 2020 case management conference.

1. **Request for Modifications to Case Management Schedule:**

The parties are meeting and conferring about jointly proposing modifications to CMO 22 which would extend certain discovery beyond April 1, 2021, without disruption to existing deadlines for Daubert briefing and hearings, and include a parallel track for Class Certification briefing in this CMO. The parties hope to present a joint proposal by tomorrow's conference or

request a separate conference with the Court dedicated to this subject to take place no later than early next week.

2. Manufacturer Deposition Issues:

Defendants' liaison counsel requested at the most recent status conference that the Court should determine the number of depositions permitted to taken by Plaintiffs of API and finished dose manufacturer witnesses, and the length of the depositions. Based upon ongoing discussions, Defendants have agreed that it is premature to address the length of depositions, thus that is not an issue. The only defendant challenging the number of depositions requested to date is ZHP, so that is the only Defendant as to which there is an issue to be discussed. It is likely that there will not be such a dispute with the other Defendants, and there is no reason to argue a hypothetical dispute that may never need to be addressed.

By way of background. at the writing of this letter Plaintiffs are still awaiting confirmed lists of the 30b6 witnesses who will address each 30b6 topic. The most that has been disclosed, for a few manufacturers, has been the names of those who will address 30b6 topics, and in a few cases the general areas that are expected to be addressed by various witnesses or a handful of topics a witness may address. Thus, Plaintiffs do not have a clear picture of how many and which witnesses will address which topics. Defendants have repeatedly advised that they have until December 23, 2020 to make these disclosures. With the exception of ZHP it is premature to argue about the number of witnesses to be deposed when no other Defendant has objected to the number identified by Plaintiffs to date, and frankly Plaintiffs do not believe there will or should

be such a dispute to be resolved as Plaintiffs have significantly limited the numbers of witnesses targeted for depositions.

On December 18, 2020, Plaintiffs discussed the witnesses to be produced by ZHP. ZHP had provided a list of some of the witnesses prioritized by Plaintiffs, with dates offered. Plaintiffs accepted the dates for four of the witnesses, subject to later discussion on the length of the depositions. As to the rest, Plaintiffs raised questions. For example, Jun Du, who resides in New Jersey, was offered in March, 2021 (and will not be designated on any 30b6 topics). **Plaintiffs questioned the decision not to designate Mr. Du to testify regarding any 30b6 topics, asked to depose Mr. Du up front at the start in January or early February, 2021, and were told that Mr. Du is unavailable at that time as he is traveling to China in January!** Similarly, every witness who resides in China, inclusive of all of the 30b6 witnesses addressing the core issues such as testing, the development of the manufacturing process, and cGMP and quality assurance activities, has been offered in March, with several during the last days before, and in one case on the date Plaintiffs' expert reports are due. During the December 18, 2020 call defense counsel advised that it is impossible to produce these witnesses, whose testimony is critical to Plaintiffs' expert reports in many cases, until March. Plaintiffs were advised this is due to quarantine issues and the loss of the entire month of February due to the holiday in China. Thus, the first month and a half of the mere 2 and one-half months allotted to take depositions cannot be used to depose the key liability/general causation witnesses from ZHP who are needed for Plaintiffs to understand masses of documents, and advance expert reports. ZHP did agree to try to alter the scheduling within the month of March, which is marginally

helpful but not a solution to the overall problem of bottlenecking key testimony from ZHP, and likely other Defendants, in the final days before expert reports are due. In light of those discussions, Plaintiffs expect that ZHP will not again state that Plaintiffs should be forced to accept the dates offered by ZHP.

This issue is very difficult and compounds the tremendous time squeeze that is being put on the Plaintiffs to conduct depositions of all manufacturer defendants, and produce expert reports in a matter of a few months. This is notwithstanding that the Defendants have been given multiple lengthy extensions and well over a year to produce their documents, beginning with the core discovery documents. It is thus very important that whatever scheduling is confirmed is equitable, and not severely prejudice Plaintiffs' development of the deposition testimony and expert reports.

3. ZHP Witness Disputes

At the outset it is important to remind the Court of the complex, interrelated corporate organizational structure for ZHP, since the "ZHP" witnesses to be deposed are in numerous cases employed by ZHP subsidiaries and affiliates that defense counsel asserts are truly separate entities, but who are acknowledged to be necessary to respond to various topics. Plaintiffs seek to depose individuals from six ZHP entities:

(1) ZHP itself,

(2) Shanghai Syncores (which developed ZHP's manufacturing process for Valsartan API),

(3) Prinbury (which developed the manufacturing process for Valsartan finished dose),

(4) Huahai US (ZHP's U.S. agent to the FDA and at least partially responsible for ZHP's sales, as recognized by ZHP's proffer of Eric Iozzia, Director of Sales at Huahai US, who reports to ZHP's sales department, as a deponent),

(5) Prinston (another entity that handles parts of ZHP's regulatory affairs in the U.S.), and

(6) Solco (who sold and distributed ZHP's finished dose Valsartan in the U.S.).

Plaintiffs have requested the depositions of 20 witnesses under the ZHP umbrella, broken down as follows:

(1) John Iozzia, Director of Sales at Huahai US **(agreed)**,

(2) Lijie Wang, Vice President of Regulatory Affairs at Prinston **(agreed)**,

(3) Remonds Gergis, Vice President of Quality Assurance at Prinston **(agreed)**.

(4) Hai Wang, President of Solco (formerly at Huahai US and Prinston) **(agreed)**,

(5) Jun Du, CEO of Prinbury, Huahai US, Prinston, and Solco **(agreed)**,

(6) Jay (Jie) Wang, Vice President of Business Development at ZHP **(agreed)**,

(7) Linda (Lihong) Lin, Director of Regulatory Affairs at ZHP **(agreed)**,

(8) Peng Dong, Deputy Director of Technology (Manufacturing), Department I at ZHP **(agreed)**,

(9) Hong (Eric) Gu, President of Shanghai Syncores **(agreed)**,

(10) Minli Zhang, Director of Finished Dose Formulation Quality at ZHP **(agreed)**,

(11) Qiangming Li, Senior Director of Analysis at ZHP **(agreed)**,

(12) Min Li, Vice President of Analysis and Testing at ZHP **(agreed)**,

(13) Jucai Ge, Director of API Quality Assurance at ZHP **(agreed)**,

(14) Xiaodi Guo, Vice President of Huahai US and Prinston **(agreed) (**ZHP has agreed to Mr. Guo as a deponent; however, he is currently "stuck" in China, and the Parties do not know when he will be able to return to the U.S., where the Parties intend to take his deposition),

(15) Yuelin Hu, Assistant Director of Quality Operation, Department I, at ZHP (**disputed)**,

(16) Yanfeng (Lucy) Liu, Deputy Director & Manager of API Regulation, at ZHP (**disputed**),

(17) Fengyang (Xavier) Tang, Assistant Manager of Business Development, Group I, at ZHP **(disputed)**,

(18) Mi (Karen) Xu, Senior Director of Market Development at ZHP (**disputed)**,

(19) Eric Tsai, General Manager of Prinbury **(disputed)**, and

(20) Baohua Chen, General Manager of ZHP and CEO of Shanghai Syncores **(disputed)**.

Preliminarily, Plaintiffs anticipate ZHP's primary argument against the disputed deponents to be alleged duplication with already agreed witnesses. However, ZHP has proffered such facially "duplicative" deponents in ZHP's Analysis and Testing Department: Min Li and Qiangming Li, because the subject matter is massive, and many more than the 20 witnesses requested to date have had significant involvement in key aspects of this case. Clearly, ZHP understands that Plaintiffs cannot be expected to rely solely on one witness from each of ZHP's departments. Additionally, as Plaintiffs previously noted in their last submission with the Court, many ZHP employees appeared to utilize Hotmail accounts to communicate with customers and other third-parties. Moreover, Plaintiffs have now seen in documents that ZHP employees utilized private

commercial chatting applications such as WeChat and Skype to communicate with customers. Plaintiffs believe that for some of these customer-facing employees, individual depositions are necessary to address this information. As such, Plaintiffs ask the Court to order the depositions of the following individuals:[1]

Yuelin Hu: Mr. Hu is employed by ZHP (Huahai Pharma) as the Director Assistant of Quality Operations Department-1 and has held this position since July 2005. ZHP has refused to produce Mr. Hu for deposition based upon the fact that Mr. Hu is a direct report to Jucai Ge and the assumption that Jucai Ge subsumes all the information known to Mr. Hu about issues relevant to this litigation. This assumption is incorrect. Mr. Hu was involved in high level product assurance matters, including issues pertaining to repetitive application of recovered solvents and unknown chromatography peaks identified by customers. For example, Mr. Hu was involved in an investigation beginning in 2016 of customer Sun Pharma's unknown peaks elucidating around the Toluene peak (unknown peaks surrounding the Toluene peak is what led to Novartis' 2018 investigation, and the ultimate discovery of NDMA). In many instances, Jucai Ge was not copied on emails sent to or from Mr. Hu regarding this investigation. He was also responsible for drafting a portion of the FDA 483 observation response in May 2017. In addition, he was a member of the committee that was responsible for the development of the $ZnCl_2$

[1] Plaintiffs have redacted the substance of their discussion of each disputed custodian in the letter filed on ECF because it contains extensive descriptions and quotations from documents that Defendants have over-designated as confidential. Plaintiffs will email an unredacted copy of this letter to the Court and Defendants' Liaison Counsel. The respective Defendants can then decide whether to file a motion to seal this letter and the attached Exhibits.

process, he reviewed deviations and out-of-specification testing for Valsartan and reviewed and approved deviation investigation reports related to nitrosamine impurities.

Yanfeng (Lucy) Liu: Yanfeng (Lucy) Liu served an important regulatory function at ZHP. Not only is Liu the person who signed off on the submission of the process change for ZHP, but she appeared to be the person in the regulatory division of ZHP that had responsibility for ZHP's API Customers, including Defendants Teva and Torrent. For example, throughout the relevant time period Liu was involved in answering questions from API customers about the key process change at issue from Defendant Torrent. (*See* ZHP00476678 (email from 2015), Ex. T hereto). Liu also appeared to be involved in preparing for monthly calls with Defendant Teva to discuss regulatory issues related to Teva's book of business with ZHP. (*See* ZHP02270194 (2017 email regarding monthly Teva calls), Ex. U hereto). Because many communications between the sales representatives at ZHP and appeared to occur in teleconferences, WeChat messages, and/or Hotmail (which Counsel for ZHP has stated they will not attempt to collect), Plaintiffs only ability to gather this discoverable information is through deposition of Liu, (and Tang and Xu) to obtain their personal knowledge.

Fengyang (Xavier) Tang: Xavier Tang had direct responsibility with communicating with ZHP's API Customers. Critically, Tang was one of the key people involved with communicating with Novartis, the entity that identified the Nitrosamine Peak in ZHP's Valsartan. These communications began in 2017, and included numerous recurring Skype meetings. (*See* ZHP01893902, Ex. V hereto). Indeed, during the investigation into the unknown peaks, Tang was the key point person to whom Novartis was communicating regarding

the testing specifications for those unknown peaks. (*See* ZHP00310874, Ex. W). Xavier Tang was a participant in numerous Skype meetings with Novartis regarding the peak. (*See* ZHP02125655, Ex. X). Because many of these communications between ZHP and Novartis (a non-party in this case) were had verbally and via means such as Skype, Plaintiffs only opportunity to gather the information conveyed during these meetings is through sworn testimony.

Mi (Karen) Xu: Similar to Xavier Tang, Karen Xu likewise had intimate involvement with ZHP's API Customers, including by acting as the point person with Defendant Teva. For example, Xu attended in-person meetings with key decision makers at Teva in 2016 in Barcelona. (*See* TEVA-MDL2875-00082208, Ex. Y hereto). Xu was also a participant in key monthly calls with Teva. (*See* ZHP01976459, Ex. Z hereto). Xu appears to have been involved in Teva's audits of ZHP, including potentially being present for such audits. (*See* HUAHAI-US00008050, Ex. AA hereto). Plaintiffs are entitled to discover the information of what transpired at these in-person meetings and audits, and deposing Xu provides Plaintiffs with this opportunity.

Eric Tsai: Mr. Tsai is the general manager of Prinbury BioPharm and has held that position since 2009. He is the only deponent requested of Prinbury BioPharm and ZHP has refused to produce him for deposition. Mr. Tsai Hoversaw, reviewed, and approved the formulation product development and analytical method development for Valsartan. He was also heavily involved in ZHP's response to the 2018 FDA 483 (*see, e.g.*, PRINBURY00129588, a draft document from his custodial file, Ex. B hereto). He provided specific edits to sections of

ZHP's 483 response regarding sampling and testing of raw materials, intermediates, and API, as well as the cleaning of facilities and equipment, and the quality department's responsibility to reject API batches.

Baohua Chen: Mr. Chen is the Founder and General Manager of ZHP and the CEO of Shanghai Syncores. On December 18, 2019, this Court denied Plaintiffs' request for Mr. Chen's inclusion as a custodian. However, the Court admitted, "I could be proven wrong in the future. If there is evidence in that regard, so be it." (12/18/2019 Trans. 24:14-15, Ex. A hereto). The Court added:

> I'll make it clear. The Court is not ruling at this time whether or not Mr. Chen is an appropriate deponent. That's a completely different evaluation that the Court has to consider at the relevant time. If defendant [sic] wants to depose Mr. Chen, we'll deal with the issue at that point. But in no way, shape, or form should the Court's ruling as to whether or not Mr. Chen is an appropriate custodian be deemed as a ruling as to whether or not he may be deposed in the case.

(12/18/2019 Trans. 24:20-25:2). As it turned out, ZHP had already withheld information critical to Plaintiffs' assessment of Mr. Chen's unique role at ZHP.

On October 12, 2019, nearly two weeks before Plaintiffs and the Court met with Jun Du, Prinston sent an organization chart to Deloitte in Atlanta, Georgia. (ZHP00076700, Ex. C hereto; ZHP00076708, Ex. D hereto). That organization chart shows that Mr. Chen is the only connection between ZHP, Shanghai Syncores, Prinbury, Huahai US, Prinston, and Solco. Most importantly, it states that Mr. Chen is the CEO of Shanghai Syncores, which developed the contaminating API manufacturing process. ZHP did not disclose this fact during the meet and confer regarding its custodians. The most senior executive from Syncores that ZHP disclosed

was the "President" "Eric Gu." This chart states that "Hong Gu" is the "General Manager," that "Shanghai Kesheng Drug Development Co. Ltd." is "[r]esponsible for API development," and that Mr. Chen is its CEO. In light of ZHP's more recent document production, Plaintiffs have confirmed Eric Gu also goes by Hong Gu.

On October 23, 2019, Plaintiffs met with Jun Du and were only given a few Chinese organization charts because English ones were allegedly not available. If Prinston got this chart to Deloitte in Atlanta almost two weeks earlier, then why did Plaintiffs not receive it in accordance with the Court's October 21, 2019 order? The obvious answer is that it shows how central and unique Mr. Chen's role is in ZHP's organization structure.

During their meet and confer with ZHP, Plaintiffs asked for Mr. Chen's custodial file in order to more completely assess his connection to this case. ZHP declined Plaintiffs' request, but even with the limited discovery produced to date, other documents confirm Mr. Chen's unique importance at ZHP. For example, Mr. Chen has told the FDA that he "has the ultimate authority at the firm and takes full responsibility for the company's operations." (PRINSTON00083647, Ex. E hereto). According to ZHP, Mr. Chen is a "Chemical Engineer," who "graduated from Zhejiang University of Technology in 1983 and worked in Zhejiang Haimen Pharmaceutical Factory from 1983 to 1989. He has worked in Zhejiang Huahai as General Manager since 1989. **He has wide experience in the product development and quality management of bulk drugs.**" (PRINSTON00077850, Ex. F hereto). **In fact, Mr. Chen has a Master of Science in Chemical Engineering.** (ZHP00004937, Ex. G hereto). **As of May 2014, he managed 3,800 employees, compared to Jun Du's 300.** *Id.*

Not surprisingly, Mr. Chen participated in at least eight FDA inspections. (PRINSTON00082995, Ex. H hereto (August 2013); ZHP00107709. Ex. I hereto (March 2014); PRINSTON0074125, Ex. J hereto (May 2014); PRINSTON00083027, Ex. K hereto (March 2015); PRINSTON00081549, Ex. L hereto (November 2016); ZHP00005780, Ex. M hereto (June 2017); PRINSTON00081570, Ex. N hereto (January 2018); PRINSTON00083641, Ex. O hereto (June 2019)). At the August 2013 inspection, the Vice General Manager of Quality Assurance said that he reported directly to Mr. Chen. (PRINSTONO0083002, Ex. H hereto). After that inspection, Mr. Chen "promised to correct/evaluate all discussion items and to expand the corrections to any related issues." (PRINSTON00083010). The March 2015 inspection reports explained Jun Du's role as "Main Facilitator/Interpreter," and Baohua Chen as the "most responsible person." (PRINSTON00083028, 31, Ex. K hereto). The May 2014, November 2016, and January 2018 inspection reports state that all FDA correspondence should be addressed to Mr. Chen. (PRINSTON00074128; PRINSTON00081551; PRINSTON00081574). It is clear that Mr. Chen played a central role at ZHP and that he communicated directly with the FDA. If the average FDA inspection is important enough for Mr. Chen's involvement, then this litigation must also qualify.

In the 2010 contract between ZHP and Shanghai Syncores to develop the Valsartan manufacturing process central to this case, Mr. Chen is listed as Shanghai Syncores's legal representative.[2] (ZHP0000222, an English translation, Ex. P hereto). During a November 1, 2013 meeting regarding the optimization of ZHP's API manufacturing processes, Mr. Chen

[2] Eric Gu is the only Shanghai Syncores employee offered as a deponent, and he only began working there in 2014.

targets the cost of Valsartan depending on the manufacturing process used. (ZHP02579748, the original Chinese document as described by a translator, Ex. Q hereto). Importantly, ZHP has told the FDA that it changed to the contaminating manufacturing process in order "to save money." (PRINSTON00162373, Ex. R hereto). Thus, Plaintiffs know that Mr. Chen used his central role at ZHP to exert pressure to develop and cut the cost of the manufacturing process at issue in this case. Plaintiffs are entitled to investigate this fact during a deposition after reviewing his custodial file.

Mr. Chen was also intimately involved with ZHP's recall of Valsartan. ZHP's "Protocol of Valsartan API Recall (Foreign grade)" lists Mr. Chen as the first member of the "Recall Group," and that group does not include Jun Du, who is the CEO of all three of ZHP's U.S. subsidiaries, which are all based in New Jersey. (ZHP00494048, Ex. S hereto). How is it possible that Mr. Chen, the CEO of the Chinese-based ZHP, would have the same documents as the New Jersey CEO of its U.S. subsidiaries? To be clear, it is not possible, especially in light of the above.

In sum, Mr. Chen is potentially the most central and important witness in this case, especially in light of strong evidence in the documents of complete indifference to testing and cGMP obligations, and deliberate efforts to withhold important information, all of which goes to ZHP's corporate culture emanating from Mr. Chen, and Plaintiffs have punitive damages claims that will point to this and other egregious conduct. Mr. Chen is the CEO of ZHP and the CEO of the ZHP subsidiary that developed the contaminating manufacturing process. He was Shanghai Syncores' legal representative for the 2010 contact between Shanghai Syncores and ZHP

regarding the development of the most recent contaminating manufacturing process, and the only other deponent offered from Shanghai Syncores is Hong (Eric) Gu, who started working at the company in 2014. (ZHP0000222, an English translation, Ex. P hereto). According to this improperly withheld organization chart, "[a]ll the VP or directors are reported to Baohua Chen[] Directly." (ZHP00076709, Ex. D hereto). They do not report through Jun Du. Mr. Chen was even the head of the "Recall Group" for Valsartan. (ZHP00494048, Ex. S hereto). ZHP has admitted that adopting the contaminating manufacturing process was a business decision. (PRINSTON00162373, Ex. R hereto). ZHP cannot credibly claim that Mr. Chen did not make this decision when he is its CEO as well as the CEO of the subsidiary that developed the process, and "[h]e has wide experience in the product development and quality management of bulk drugs." (PRINSTON00077850, Ex. F hereto). As a result, Plaintiffs ask this Court to order Mr. Chen's deposition and the production of his custodial file.

4. Teva TAR Protocol

Plaintiffs and Teva reached agreement on the Protocol to govern Teva's continued search of custodial documents, and the Protocol is being submitted to the Court under separate cover.

5. Plaintiffs' Additional Discovery of Wholesaler and Retail Pharmacy Defendants

On December 8, 2020, Plaintiffs served Wholesaler and Retail Pharmacy Defendants with two forms of draft discovery: (i) second sets of document requests, and (ii) Rule 30(b)(6) deposition notices. (*See* Exs. BB & CC). Plaintiffs' intention was to confer with Defendants about the scope, for the final document requests and notices to be entered by the Court, as have been the practice in this litigation with all other discovery to date. However, Wholesaler and

Retail Pharmacy Defendants have refused to meet and confer about Plaintiffs' draft discovery. Instead, Wholesaler and Retail Pharmacy Defendants claim that any additional discovery directed to them should occur after the current April 1 discovery deadline, or even after an order on class certification.

This is improper. The current discovery schedule calls for the completion of all fact discovery by April 1, 2021. Plaintiffs cannot agree to serve – let alone even discuss – additional discovery on two tiers of Defendants until *after* the current fact discovery deadline.

Additionally, Plaintiffs' additional document requests and deposition notices are narrowly targeted on important liability and class issues. The document requests largely focus on very discrete, highly relevant documents; for example, warranties received and made about VCDs, inventory management policies, and purchase/sales agreements for VCDs. Notably, Retail Pharmacy and Wholesaler Defendants do not even object or argue to the substance of any requests; they merely claim they should not even have to deal with this discovery until many months from now.

Plaintiffs had agreed to table additional discovery of Wholesaler and Retail Pharmacy Defendants when Plaintiffs negotiated their first sets of document requests to these Defendants (which took from December 2019 to July 2020). The expectation at that time was that the parties' efforts should initially focus on Manufacturer Defendants, with additional discovery of Wholesaler and Retail Pharmacy Defendants to follow. The time for that additional discovery to follow, however, is now.

Similarly, Plaintiffs' corporate deposition notices are tailored to the issues unique to the Wholesaler and Retail Pharmacy Defendants in this case. There is no basis, in the existing schedule or otherwise, for these Defendants to unilaterally resist deposition discovery until *after* the Court's April 1, 2021 deadline.

For these reasons, given Wholesaler and Retail Pharmacy Defendants refusal to even meet and confer about Plaintiffs' proposed deposition notices and document requests, the Court should find these Defendants have waived any objections to them and enter Plaintiffs' notices and document requests as Exhibits DD & EE.

6. Issues With Wholesaler Defendants' DFSs and Plaintiffs' First Set of Document Requests to Wholesaler Defendants

Plaintiffs are pleased to report that, since the last CMC, the parties have agreed to a schedule for Wholesalers' completion of Defendant Fact Sheets.

There remains, however, ripe disputes concerning Wholesaler Defendants' responses and objections to Plaintiffs' first set of documents (which were entered in July 2020, after months of negotiation, letter briefing, and argument). Plaintiffs first raised these issues with Wholesaler Defendants on November 18, 2020. (*See* Ex. FF hereto). Following a meet and confer on December 1, Wholesaler Defendants did not follow up again until December 17 but only to respond that *any* issue concerning these prior requests should be handled by way of Plaintiffs serving *new* document requests. (*See* Ex GG hereto). This of course is ironic because, as discussed above, Wholesaler Defendants have refused even to meet and confer about Plaintiffs' draft second set of document requests, and further contend any further discovery of them should take place *after* the current April 1 discovery deadline.

First, all three Wholesaler Defendants have objected to producing data responsive to the court-ordered document requests on the basis that the Drug Supply Chain Security Act ("DSCSA") prohibits them from doing so, even under court order. (*See* Ex. GG hereto(Wholesaler Defendants' Objs. & Resps.)). Wholesaler Defendants never raised this issue in the months-long meet and confer process, in letter briefing to the Court, or during lengthy oral argument. Thus, any belated "objection" to producing responsive data has been waived. Further, the Confidentiality Order in this case vitiates any confidentiality concerns. Finally, Wholesaler Defendants' assertion that Plaintiffs should just get bits of this same data from Manufacturer and Retailer Defendants, and piece it together themselves to infer what Wholesaler Defendants might possess, is no solution. As the party resisting discovery, it is Wholesaler Defendants' burden to show that the data they possess is duplicative of data from other sources. They cannot hoist upon Plaintiffs the burden of guessing what data each Manufacturer or Retail Pharmacy Defendant might send or receive to each Wholesaler Defendant, and in turn what might reside in each Wholesaler Defendant's files. In lieu of the data production, Plaintiffs are not opposed to a stipulation to the effect that each Wholesaler Defendant has and maintains all of the data required by the DSCSA for VCDs, and specifying what data fields they receive from each Manufacturer, or send to each Retail Pharmacy Defendant. But to date, Wholesaler Defendants have not been willing to discuss the contours of such a stipulation. Thus, Plaintiffs have no choice but to insist that Wholesaler Defendants produce that which they *agreed* to produce in the court-ordered document requests. The Court's recent Motion to Dismiss ruling rejecting preemption under the DSCSA only serves to highlight that the DSCSA's provisions were meant to co-exist with judicial proceedings. Wholesaler Defendants' arguments that

they are prohibited by the DSCSA from producing this information should be flatly rejected at this point.

Second, each Wholesaler Defendant has heavily redacted agreements they have for the purchase or sale of VCDs. They also treated the agreed-upon document request calling for "documents sufficient to identify a list of your significant employees involving in managing the recall of VCDs" as an interrogatory. Instead of producing documents, they each provided a narrative answer identifying a single employee. (*See* Exs. GG (at Resps. to Req. No. 16)). After Plaintiffs waited for weeks to hear Wholesaler Defendants' final position on all of this, Wholesaler Defendants responded that these issue are subsumed by Plaintiffs' new draft document requests – the same requests Wholesaler Defendants refuse to meet and confer about, and which they say should not be answered until after the April 1 fact discovery deadline. Wholesaler Defendants cannot have it both ways. They either need to produce documents in response to the existing court-ordered document requests, or in response to Plaintiffs' proposed second set of document requests. They cannot leave the production of these highly relevant documents in limbo by gaming the meet and confer process and court-ordered discovery schedule.

7. Deposition Protocol Addendums:

Plaintiffs have reached agreement with the Defendants regarding the Chinese and Indian national addendums. Teva previously advised that there may not be a need to pursue a third Addendum, and would forward a proposed revised version if it becomes necessary. That Addendum is awaited and the parties can update the Court at the conference.

8. Torrent Confidentiality Designations:

Plaintiffs are in receipt of Torrent's submission to the Court. First, Plaintiffs reiterate that Torrent did not timely move to maintain the confidentiality designations per the terms of the Confidentiality Order. This is not disputed. Plaintiffs maintain that none of the documents reach the level of sensitivity required to justify the designations, and in particular information regarding the recalls, the manufacturing process changes, internal scrutiny of quality assurance issues, and internal discussion of the need to reimburse customers. All must be seen in the larger context of a worldwide health and safety crisis resulting from this and the other Defendants' carelessness fueled by a motive to cut costs for profit reasons, the details of which have been disclosed to a large extent through FDA communications. The public health ramifications of this crisis outweighs all of the arguments for confidentiality, to the extent any of these documents may be seen to approach the level of sensitivity needed to justify these designations. Plaintiffs request an order de-designating the five exemplars at issue, and directing Torrent to bring its entire document production into compliance with the Court's ruling.

9. Joint Stipulation Regarding Dismissal of Torrent Private Ltd.

Torrent filed a joint stipulation regarding the dismissal of Torrent Private and the acceptance of service of Torrent Pharmaceuticals on November 13, 2020. (ECF 630). Plaintiffs respectfully ask the Court to approve this joint stipulation.

Respectfully,

ADAM M. SLATER